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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/034,694	12/28/2001	Steven D. Kruse	1416.49US01	2324

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EXAMINER

SWEET, THOMAS

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 11/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/034,694

Applicant(s)

KRUSE ET AL.

Examiner

Thomas J Sweet

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 29 is/are allowed.
- 6) ☒ Claim(s) 1-15, 19-21 and 23-26 is/are rejected.
- 7) ☒ Claim(s) 16-18, 22 and 27-28 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other: ____

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DETAILED ACTION

Claim Rejections - 35 USC § 102 The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-4, 6-7, 9-10, 14-15, 23 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Goldstein et al (US 5899937). Goldstein et al discloses test apparatus and method for testing a stented heart valve with a flexible membrane (fig. 2) by applying backwards pressure (Col 10, lines 44-47) to the valves in the flow blocking position. Based of figure 2 the valve does not open fully in the forward flow direction more than about 80% of the cross sectional area. The test apparatus (fig. 3) comprises a cyclic pressure applicator (pump chamber) a conduit connected to the pressure applicator and a stent test structure mounted in the conduit (fig. 2).

With regard to claim 4, Column 10, lines 44-47 states that the peak pressure would be 120 mm Hg.

With regard to claim 14, see the abstract.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 5, 11-13, 19-21 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldstein et al in view of Pietsch et al (US 4778461). Goldstein et al discloses a test apparatus and method for testing a stented heart valve as discussed above. However, Goldstein et al remains silent as to the heart valve stent having commissure posts and does not disclose the heart valve membrane being made of polyurethane or silicone integrally cast with the stent. Heart valves having commissure posts and having a membrane of polyurethane or silicone integrally cast with the stent are well known in the art of heart valves as demonstrated by Pietsch et al. It would have been obvious to one of ordinary skill in the art at the time the invention was made to test the stent of Pietsch et al in the test apparatus of Goldstein et al in order to perform tests on the valve of Pietsch et al.

With regard to claim 5, the commissure post would inherently deflect inward the equivalent amount that they would when subject to a pulse duplicator at physiological condition, since the test apparatus functions at physiological condition.

Claims 8 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldstein et al in view of Eberhardt (US 5176153). Goldstein et al discloses a test apparatus and method for testing a stented heart valve as discussed above. However, Goldstein et al does not

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disclose testing at a frequency of from about 1000 to about 6000 cycles per minute. Eberhardt teaches another a test apparatus and method for testing a stented heart valve which includes testing at a frequency of up to 400 cycles per second (Col 6 lines 29-43, i.e. up to 24000 cycles per minute) for the purpose of accelerated wear and fatigue testing. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the test apparatus of Goldstein et al in order to test at a frequency of up to 24000 cycles per minute (including 1000-6000 cycles per minute) as taught by Eberhardt in order to perform accelerated wear and fatigue tests.

Response to Arguments

Applicant's arguments, see page 6, filed 10/14/03, with respect to claim 5 have been fully considered and are persuasive. The rejection under 35 USC § 112 of claim 5 has been withdrawn.

Applicant's arguments, see pages 7 and 8, filed 10/14/03, with respect to claim 29 have been fully considered and are persuasive. The rejection under 35 USC § 102 of claim 29 has been withdrawn.

Applicant's arguments filed 10/14/03 regarding claims 1-15, 19-21, 23-26 have been fully considered but they are not persuasive. The applicant defines "does not fully open" as opens no more than about 80% of the full open lumen at the inflow edge of the stent. The nozzle of Goldstein et al tapers to about 80% of the full open lumen, so a valve installed in the nozzle when fully open against the walls of the nozzle would only open about 80% of the full open

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lumen. As "does not fully open" is defined by the applicant, Goldstein et al anticipates the rejected claims.

Allowable Subject Matter

Claim 29 is allowed.

Claims 16-18, 22 and 27-28 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas J Sweet whose telephone number is (703) 308-4018. The examiner can normally be reached on 6:30 am - 5:00pm, M-Th.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine M McDermott can be reached on (703) 308-2111. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-2708.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

tjs



CORRINE McDERMOTT
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